



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/589,450

05/04/2007

Malte Peters

DEBE:069US/10612950

5684

32425 7590 08/15/2008
FULBRIGHT & JAWORSKI L.L.P.
600 CONGRESS AVE.
SUITE 2400
AUSTIN, TX 78701

EXAMINER

DUFFY, BRADLEY

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

08/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/589,450	Applicant(s) PETERS ET AL.	
	Examiner BRADLEY DUFFY	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The preliminary amendment filed August 11, 2006 is acknowledged and has been entered. Claims 2-4, 7-9, 12 and 15-22 have been amended. Claims 23-25 have been newly added.
2. Claims 1-25 are pending in the application and are currently subject to restriction.

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 9-11 and 22, insofar as the claims are drawn to a method of treating breast cancer in a human patient by administering to said patient a human immunoglobulin specifically binding to the human EpCAM antigen, said immunoglobulin exhibiting a serum half-life of at least 15 days, said method comprising the step of administering said immunoglobulin no more frequently than once every week.

Group II, claims 9 and 22, insofar as the claims are drawn to a method of treating hepatocellular carcinoma in a human patient by administering to said patient a human immunoglobulin specifically binding to the human EpCAM antigen, said immunoglobulin exhibiting a serum half-life of at least 15 days, said method comprising the step of administering said immunoglobulin no more frequently than

once every week.

Group III, claims 9 and 22, insofar as the claims are drawn to a method of treating cholangiocellular cancer in a human patient by administering to said patient a human immunoglobulin specifically binding to the human EpCAM antigen, said immunoglobulin exhibiting a serum half-life of at least 15 days, said method comprising the step of administering said immunoglobulin no more frequently than once every week.

Group IV, claims 9 and 22, insofar as the claims are drawn to a method of treating stomach cancer in a human patient by administering to said patient a human immunoglobulin specifically binding to the human EpCAM antigen, said immunoglobulin exhibiting a serum half-life of at least 15 days, said method comprising the step of administering said immunoglobulin no more frequently than once every week.

Group V, claims 9 and 22, insofar as the claims are drawn to a method of treating colon cancer in a human patient by administering to said patient a human immunoglobulin specifically binding to the human EpCAM antigen, said immunoglobulin exhibiting a serum half-life of at least 15 days, said method comprising the step of administering said immunoglobulin no more frequently than once every week.

Group VI, claims 9-11 and 22, insofar as the claims are drawn to a method of treating prostate cancer in a human patient by administering to said patient a human immunoglobulin specifically binding to the human EpCAM antigen, said immunoglobulin exhibiting a serum half-life of at least 15 days, said method comprising the step of administering said immunoglobulin no more frequently than once every week.

Group VII, claims 9 and 22, insofar as the claims are drawn to a method of treating head and neck cancer in a human patient by administering to said patient a human immunoglobulin specifically binding to the human EpCAM antigen, said immunoglobulin exhibiting a serum half-life of at least 15 days, said method comprising the step of administering said immunoglobulin no more frequently than once every week.

Group VIII, claims 9 and 22, insofar as the claims are drawn to a method of treating skin cancer (melanoma) in a human patient by administering to said patient a human immunoglobulin specifically binding to the human EpCAM antigen, said immunoglobulin exhibiting a serum half-life of at least 15 days, said method comprising the step of administering said immunoglobulin no more frequently than once every week.

Group IX, claims 9 and 25, insofar as the claims are drawn to a method of treating ovarian cancer in a human patient by administering to said patient a human immunoglobulin specifically binding to the human EpCAM antigen, said immunoglobulin exhibiting a serum half-life of at least 15 days, said method comprising the step of administering said immunoglobulin no more frequently than once every week.

Group X, claims 9 and 25, insofar as the claims are drawn to a method of treating endometrial cancer in a human patient by administering to said patient a human immunoglobulin specifically binding to the human EpCAM antigen, said immunoglobulin exhibiting a serum half-life of at least 15 days, said method comprising the step of administering said immunoglobulin no more frequently than once every week.

Group XI, claims 9 and 25, insofar as the claims are drawn to a method of treating cervix cancer in a human patient by administering to said patient a human

immunoglobulin specifically binding to the human EpCAM antigen, said immunoglobulin exhibiting a serum half-life of at least 15 days, said method comprising the step of administering said immunoglobulin no more frequently than once every week.

Group XII, claims 9 and 22, insofar as the claims are drawn to a method of treating kidney cancer in a human patient by administering to said patient a human immunoglobulin specifically binding to the human EpCAM antigen, said immunoglobulin exhibiting a serum half-life of at least 15 days, said method comprising the step of administering said immunoglobulin no more frequently than once every week.

Group XIII, claims 9 and 22, insofar as the claims are drawn to a method of treating lung cancer in a human patient by administering to said patient a human immunoglobulin specifically binding to the human EpCAM antigen, said immunoglobulin exhibiting a serum half-life of at least 15 days, said method comprising the step of administering said immunoglobulin no more frequently than once every week.

Group XIV, claims 9 and 22, insofar as the claims are drawn to a method of treating gastric cancer in a human patient by administering to said patient a human immunoglobulin specifically binding to the human EpCAM antigen, said immunoglobulin exhibiting a serum half-life of at least 15 days, said method comprising the step of administering said immunoglobulin no more frequently than once every week.

Group XV, claims 9 and 22, insofar as the claims are drawn to a method of treating a cancer of the small intestine in a human patient by administering to said patient a human immunoglobulin specifically binding to the human EpCAM antigen, said immunoglobulin exhibiting a serum half-life of at least 15 days, said method

comprising the step of administering said immunoglobulin no more frequently than once every week.

Group XVI, claims 9 and 22, insofar as the claims are drawn to a method of treating liver cancer in a human patient by administering to said patient a human immunoglobulin specifically binding to the human EpCAM antigen, said immunoglobulin exhibiting a serum half-life of at least 15 days, said method comprising the step of administering said immunoglobulin no more frequently than once every week.

Group XVII, claims 9 and 22, insofar as the claims are drawn to a method of treating pancreas cancer in a human patient by administering to said patient a human immunoglobulin specifically binding to the human EpCAM antigen, said immunoglobulin exhibiting a serum half-life of at least 15 days, said method comprising the step of administering said immunoglobulin no more frequently than once every week.

Group XVIII, claims 9 and 22, insofar as the claims are drawn to a method of treating gall bladder cancer in a human patient by administering to said patient a human immunoglobulin specifically binding to the human EpCAM antigen, said immunoglobulin exhibiting a serum half-life of at least 15 days, said method comprising the step of administering said immunoglobulin no more frequently than once every week.

Group XIX, claims 9 and 22, insofar as the claims are drawn to a method of treating a cancer of the bile duct in a human patient by administering to said patient a human immunoglobulin specifically binding to the human EpCAM antigen, said immunoglobulin exhibiting a serum half-life of at least 15 days, said method comprising the step of administering said immunoglobulin no more frequently than once every week.

Group XX, claims 9 and 22, insofar as the claims are drawn to a method of treating esophagus cancer in a human patient by administering to said patient a human immunoglobulin specifically binding to the human EpCAM antigen, said immunoglobulin exhibiting a serum half-life of at least 15 days, said method comprising the step of administering said immunoglobulin no more frequently than once every week.

Group XXI, claims 9 and 22, insofar as the claims are drawn to a method of treating a cancer of the salivatory glands in a human patient by administering to said patient a human immunoglobulin specifically binding to the human EpCAM antigen, said immunoglobulin exhibiting a serum half-life of at least 15 days, said method comprising the step of administering said immunoglobulin no more frequently than once every week.

Group XXII, claims 9 and 22, insofar as the claims are drawn to a method of treating a cancer of the thyroid gland in a human patient by administering to said patient a human immunoglobulin specifically binding to the human EpCAM antigen, said immunoglobulin exhibiting a serum half-life of at least 15 days, said method comprising the step of administering said immunoglobulin no more frequently than once every week.

Group XXIII, claims 13-16, drawn to a human immunoglobulin specifically binding to the human EpCAM antigen, compositions thereof and a human immunoglobulin specifically binding to the human EpCAM antigen comprising a heavy chain with an amino acid sequence as set out in SEQ ID NO:1 and a light chain with an amino acid sequence as set out in SEQ ID NO:2.

4. Claims 1-8, 12, 17-21 and 23-24 are linking claims, linking the inventions of

Groups I-XXII. Claim 22 is a linking claim, insofar as it links the inventions of Groups IX-XI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

5. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

To have a general inventive concept under PCT Rule 13.1, the inventions need to be linked by a special technical feature. The technical feature recited in claim 1 is administering to a human patient a human immunoglobulin specifically binding to the human EpCAM antigen, said immunoglobulin exhibiting a serum half-life of at least 15 days, said method comprising the step of administering said immunoglobulin no more frequently than once every week. This claim lacks inventive step over Lewis (Curr. Opin. Mol. Ther., 5:433-436, 2003, IDS filed 05/29/2007) in view of US 20030092160 A1 (Bout et al, 2003). Lewis teaches methods of administering a human-mouse chimeric immunoglobulin that specifically binds human EpCAM antigen to human patients with breast cancer every three weeks and that the immunoglobulin can have a half life of 17 days (see entire document, e.g., abstract and page 434). US 20030092160 A1 teaches

the advantages of making human immunoglobulins to administer to humans and that human immunoglobulins that specifically bind human EpCAM antigen are known in the art. Therefore, claim 1 lacks inventive step, because it would have been obvious to one of ordinary skill in the art at the time the invention was made to administer to a human patient a human immunoglobulin specifically binding to the human EpCAM antigen, said immunoglobulin exhibiting a serum half-life of at least 15 days, said method comprising the step of administering said immunoglobulin no more frequently than once every week, in view of these references. Therefore the technical feature recited in claim 1 is not special.

For these reasons, the special technical feature of the invention of Group I is administering to a breast cancer patient a human immunoglobulin specifically binding to the human EpCAM antigen.

The special technical feature of the invention of Group II is administering to a hepatocellular carcinoma patient a human immunoglobulin specifically binding to the human EpCAM antigen.

The special technical feature of the invention of Group III is administering to a cholangiocellular cancer patient a human immunoglobulin specifically binding to the human EpCAM antigen.

The special technical feature of the invention of Group IV is administering to a stomach cancer patient a human immunoglobulin specifically binding to the human EpCAM antigen.

The special technical feature of the invention of Group V is administering to a colon cancer patient a human immunoglobulin specifically binding to the human EpCAM antigen

The special technical feature of the invention of Group VI is administering to a prostate cancer patient a human immunoglobulin specifically binding to the human EpCAM antigen.

The special technical feature of the invention of Group VII is administering to a head and neck cancer patient a human immunoglobulin specifically binding to the human EpCAM antigen.

The special technical feature of the invention of Group VIII is administering to a skin cancer (melanoma) patient a human immunoglobulin specifically binding to the human EpCAM antigen.

The special technical feature of the invention of Group IX is administering to an ovarian cancer patient a human immunoglobulin specifically binding to the human EpCAM antigen

The special technical feature of the invention of Group X is administering to a endometrial cancer patient a human immunoglobulin specifically binding to the human EpCAM antigen.

The special technical feature of the invention of Group XI is administering to a cervix cancer patient a human immunoglobulin specifically binding to the human EpCAM antigen.

The special technical feature of the invention of Group XII is administering to a kidney cancer patient a human immunoglobulin specifically binding to the human EpCAM antigen.

The special technical feature of the invention of Group XIII is administering to a lung cancer patient a human immunoglobulin specifically binding to the human EpCAM antigen

The special technical feature of the invention of Group XIV is administering to a gastric cancer patient a human immunoglobulin specifically binding to the human EpCAM antigen.

The special technical feature of the invention of Group XV is administering to a cancer of the small intestine patient a human immunoglobulin specifically binding to the human EpCAM antigen.

The special technical feature of the invention of Group XVI is administering to a liver cancer patient a human immunoglobulin specifically binding to the human EpCAM antigen.

The special technical feature of the invention of Group XVII is administering to a pancreas cancer patient a human immunoglobulin specifically binding to the human EpCAM antigen

The special technical feature of the invention of Group XVIII is administering to a gall bladder cancer patient a human immunoglobulin specifically binding to the human EpCAM antigen.

The special technical feature of the invention of Group XIX is administering to a cancer of the bile duct patient a human immunoglobulin specifically binding to the human EpCAM antigen.

The special technical feature of the invention of Group XX is administering to an esophagus cancer patient a human immunoglobulin specifically binding to the human EpCAM antigen.

The special technical feature of the invention of Group XXI is administering to a cancer of the salivatory glands patient a human immunoglobulin specifically binding to the human EpCAM antigen

The special technical feature of the invention of Group XXII is administering to a cancer of the thyroid gland patient a human immunoglobulin specifically binding to the human EpCAM antigen.

The special technical feature of the invention of Group XXIII is making a human immunoglobulin specifically binding to the human EpCAM antigen.

Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined and, if necessary, a species of invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention. The election of an invention may be made with or without traverse. To reserve a right to

petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is

found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached at Monday through Friday from 7:00 AM to 4:30 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for

Art Unit: 1643

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Brad Duffy
571-272-9935

/Stephen L. Rawlings/
Primary Examiner, Art Unit 1643

/bd/
Examiner, Art Unit 1643
August 14, 2008